REMARKS

Claims 10 and 11 have been canceled without prejudice or disclaimer. Claims 1 and 4 have been amended, and new claims 14 and 15 have been added. Upon entry of these amendments, Claims 1-9 and 12-15 will be pending, of which claims 6-9 and 12-13 are withdrawn as directed to non-elected subject matter.

Amendments to the Claims

Claims 1 and 4 have been amended to remove reference to precursors and derivatives, and reformatted by removing commas that are inconsistent with the revised structure of these claims.

Claims 1 and 4 also have been amended to recite that the administration is performed orally. This is supported in the original specification for a pharmaceutical composition at page 8, line 5. A food is implicitly understood to be administered orally.

Claims 1 and 4 further have been amended to recite that the step of administration is to a bird or mammal whose intestinal flora is out of balance. Support for this amendment is found in the original specification at page 6, lines 14-21. In that passage, an improvement of the intestinal flora is defined as either (1) a change of the composition of the intestinal flora

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whereby the proportion in the population of harmful bacteria is reduced, or (2) as stabilization of the intestinal flora in a condition in which it is in balance. Thus, the definition refers to either (1) changing the composition when the intestinal flora is out of balance or (2) stabilizing the composition when it is in balance. These are two complementary conditions, and implicitly either one or the other must be true. While the passage does not explicitly state that condition (1) refers to the flora as being "out of balance", such is implicitly the meaning of the passage, because it is contrasted with condition (2), where the passage explicitly states that the flora is "in balance". The passage therefore describes two alternative methods, the first being a rectification of an intestinal flora that is out of balance, and the second being a stabilization of an intestinal flora that is in balance. The state of the intestinal flora of being out of balance, which corresponds to an excess proportion of the population represented by harmful bacteria, is what is being addressed by the methods of claims 1 and 4.

The specification further explains what is meant by the condition where the intestinal flora is out of balance in the immediately following passage, at page 6, lines 22-27, which provides support for new claims 14 and 15. The passage states

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that harmful bacteria are associated with diarrhea, infections of the gastrointestinal tract, liver damage, and/or intestinal cancer. The passage also states that useful bacteria promote, and by implication harmful bacteria inhibit, stimulating immunological functions, reducing problems resulting from distention due to gas, improving digestion, absorption of nutrients, and synthesis of vitamins. Therefore, this passage supports the new claims, which recite administering the food or pharmaceutical composition to a bird or mammal suffering from one or more of diarrhea, an infection of the gastrointestinal tract, liver damage, intestinal cancer, poor immunological function, distension due to gas, poor digestion, poor absorption of nutrients, and vitamin deficiency.

No new matter has been added.

Rejection Under 35 U.S.C. §§ 101 and 112, Second Paragraph

Claims 10-11 are rejected as being indefinite and as reciting non-statutory subject matter. Claims 10-11 have been canceled, rendering the rejection moot.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 1-5 are rejected as allegedly lacking enablement over their full scope. The rejection is respectfully traversed.

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The rejection refers to the step of administration, which is not limited to any particular route of administration, and is therefore allegedly not enabled over the full scope. The Examiner has stated, however, that the claims are enabling for oral administration. The claims have been amended to limit the administration to oral administration. Therefore, the present claims are believed to be fully enabled, and withdrawal of the rejection is respectfully requested.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 1-5 are rejected as allegedly indefinite for reciting "improving the composition of the intestinal flora" and for reciting "precursor" and "derivative" with respect to the sphingolipids. The rejection is respectfully traversed.

The recitation of precursors and derivatives has been deleted from the claims, rendering that part of the rejection moot.

As to "improving the composition of the intestinal flora", this term is defined in the specification at page 6, lines 14-27. The specification specifically defines this phrase as referring to either "a change of the intestinal flora of a bird or mammal, whereby the proportion in the population of harmful bacteria is reduced" or "stabilization of the flora in a condition in which it

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is in balance". The present amendments of claims 1 and 4 have further clarified that the claimed methods are directed to such improvements where the intestinal flora is out of balance, i.e., where there is an excess proportion of the population represented by harmful bacteria. Therefore, it would be clear to the ordinary skilled person, based on the language of the claims in view of the specification, that the claims refer to a method of improving the composition of the intestinal flora wherein the improvement takes the form of reducing the proportion of harmful bacteria in the intestinal flora.

The specification further clarifies what is meant by "harmful bacteria" at page 6, lines 17-27. First, it is pointed out that the skilled person is aware of species of bacteria that are generally known to be healthy for the intestinal flora (such as *Lactobacillus* and *Bifidobacterium* spp.) as well as species that are known to be harmful (such as *Clostridium difficile*). Examples are also provided of conditions that are associated with harmful bacteria (diarrhea, gastrointestinal infections, liver damage, and intestinal cancer) and conditions associated with healthy bacteria (such as inhibition of the growth of harmful bacteria, stimulation of immune function, reduction of bloating, improved digestion and absorption of nutrients, and vitamin synthesis).

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Thus, the specification makes clear what is meant by harmful bacteria and their overgrowth in the intestinal flora, and the phrase "improving the composition of the intestinal flora" is clear and definite. The withdrawal of the rejection is respectfully requested.

Rejection Under 35 U.S.C. § 102(b)

Claims 1 and 4 are rejected as allegedly anticipated by US 6239297 ('297). The rejection is respectfully traversed.

The rejection alleges that '297 discloses oral administration of sphingosine derivatives. The rejection continues by acknowledging that '297 fails to teach any effects of the sphingosine derivatives on the intestinal flora, but argues that such effects would have been inherent.

Applicants' present claims specify, however, that a sphingolipid is orally administered to a specific set of subjects, namely subjects whose intestinal flora is out of balance. Because oral administration of a sphingolipid to this set of subjects is not disclosed in '297, the claimed method is distinct from and patentably novel over the method of '297. The claimed method is not inherent to the method of '297, because '297 does not teach or suggest any particular disease or condition that is treated by

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oral administration of the disclosed sphingosine derivatives. For the same reason, the claimed method is also non-obvious over '297, which does not in any way point toward the set of avian or mammalian subjects treated in the presently claimed method.

The withdrawal of the rejection is respectfully requested.

Rejections Under 35 U.S.C. § 103(a)

Claims 1-4 are rejected as allegedly obvious over WO 0234062 (WO '062). The rejection is respectfully traversed.

WO '062 is cited as teaching that sphingomyelin plays an important role in food chemistry and in communication between and within cells. The rejection admits that WO '062 fails to appreciate any effects of sphingomyelin on improving the intestinal flora, but alleges that this feature would be inherent to sphingomyelin administration.

The WO '062 application, like the '297 patent discussed in the previous section, completely fails to teach or suggest the administration of sphingomyelin to the group of subjects recited in the present claims, namely a bird or mammal whose intestinal flora is out of balance. Therefore, the present claims are not obvious over the WO '062 application, and the rejection should be withdrawn.

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Claims 1 and 4-5 are rejected as allegedly obvious over US 6610835 ('835). The rejection is respectfully traversed.

The '835 patent is cited as teaching certain sphingolipids as modulators of neoplastic transformation and suppressors of carcinogenesis, and as recognizing that only small amounts of orally administered sphingolipids survive to the lower intestine, and consequently as recognizing a need to increase bioavailability of orally administered sphingolipids. Not surprisingly, the object of the '835 patent is to provide prodrugs of sphingolipids so as to decrease their selective cleavage in the lower GI tract and thereby increase their bioavailability. See, e.g., '835 at col. 9, lines 37-40.

The Examiner has concluded that the poor survival of sphingolipids to the lower GI tract is motivation to simply boost the level of sphingolipids by a mechanism similar to that of the present invention. However, this is not proposed in the '835 patent, which instead pursues an entirely different approach--that of synthesizing pro-drugs of sphingolipids. Indeed, the poor survival of sphingolipids in the lower GI tract, as pointed out by the Examiner, should be seen as <u>teaching away</u> from the present invention, not as rendering it obvious. Poor survivability of

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sphingolipids in the GI tract would seem to cast doubt as to whether sufficient levels of sphingolipid would survive to the lower GI tract to be effective. At a minimum, the selective cleavage of sphingolipids in the lower GI tract renders unpredictable whether the object of the present invention could be achieved.

Regardless of the relevance of the observation in '835 concerning survivability of sphingolipids in the lower GI tract, the '835 patent completely fails to teach or suggest the oral administration of sphingolipids to a set of avian and mammalian subjects whose intestinal flora is out of balance. Therefore, the claims are not obvious over '835, and the rejection should be withdrawn.

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The Examiner is encouraged to telephone the undersigned attorney to discuss any matter that would expedite allowance of the present application.

Respectfully submitted,

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